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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Michael J. Drews

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

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3738

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/765,725	Applicant(s) DREWS ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 36-55 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-22, 36-44 and 46-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/07 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 36-41,43,44,46,49,52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Lane (6371983). Lane shows (Fig. 1) a heart valve assembly that comprises a base member **25** having a generally annular shaped body and a flexible cuff **17** extending around the periphery. The assembly also includes a valve member **13** and is also multi-lobular in shape since it includes lobular leaflets (15a-c) and is attached to a multi-lobular outer frame **25**. There are also elongate guide members **23** that extend from the base and receivable through the valve member and are slidable against the valve member when inserted therein to secure or align the inner and outer frames together. Fig. 4 shows the elongate pins and complementary connectors in the

form of apertures. Fig. 5 additionally shows the second connecting member with apertures or holes **26**. The head of the pin prevents the valve member from being directed away from the base member. The valve member has channels in the form of holes for the guide members or pins. The Examiner also interprets recesses as holes or channels. The guide members are detachable since they are not integral or part of the base member. Since the guide members extend from the base, they can be said to extend from a section of the lobed based member.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lane '983. Lane is explained supra. However, Lane fails to teach a cover extending across a portion of the recess. It would have been obvious to use a reinforcement cover through the valve member tissue leaflets such that it prevents any tearing of the material forming the leaflets of the valve member, such a modification only involves routine skill in the art and would provide predictable results.

Claims 42,48,50,51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane '983 in view of Macoviak (6893459). Lane is explained supra. However, Lane fails to disclose the use of ratcheting elements and detents to join guide members with the connector or holes to space the base member or outer frame from the inner frame. Macoviak teaches (Figs. 3,4) that one of the base member or annular body has a

guide member **67** and the other component has ratchets **43** and the guide member in a guide channel **77**. Macoviak also teaches that the ratcheting provides the surgeon the ability with controlled placement of the valve member at the annulus, col. 6, lines 20-31. It would have been obvious to one of ordinary skill in the art to utilize a ratcheting system as taught by Macoviak with the components of Lane's prosthetic valve assembly such that it enables the surgeon to manipulate the distance of the valve members to be spaced apart and fit within the patient to properly implant the heart valve assembly. Regarding claim 48, it can be seen that the guide member extending into the channel **77** of Macoviak shows a rectangular cross-section.

Claims 1,2,4-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barone et al. (4705516) in view of Lane '983. Barone et al. show (Fig. 1) a multiple component heart valve assembly comprising an annular base member **b'** defining a plane and an annular body **c'** separate and disconnected from the base member and is rotatable relative to the base member about the longitudinal axis. Additionally it can be seen there are cooperating connectors or guides **2,3** respectively on the base member and annular body. The first connector can be construed to be a plurality of spaced elements along the perimeter as illustrated in a longitudinal dimension. The connectors comprise protrusions and grooves in the respective surfaces of the engaging members. Regarding claim 6, the Examiner interprets the protrusion to be resilient since it is made of a material to be permanently placed and replace a defective valve, col. 3, lines 41-44. Barone discloses the annular member comprises a valve, col. 2, lines 22,23,59-63. However, Barone et al. fail to disclose the base member and annular body are multi-

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lobular in shape or to have a flexible cuff. Lane is explained supra. It would have been an obvious expedient to vary the shape of the corresponding connecting base and annular member of the valve to be multi-lobular such that it matches the anatomical dimensions of the patient's valve structure. A change in shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the shape of the cooperating rotatable members as taught by Barone et al. as modified by Lane or the claimed multi-lobular members because both prostheses provide a rotatable assembly capable of replacing a heart valve and aligning the members during implantation.

Regarding claims 8,13 Lane is explained above. It would have been obvious to one of ordinary skill in the art to provide a flexible cuff as taught by Lane with the prosthesis of Barone et al. such that it enables the surgeon to place and conform the cuff to the tissue anatomy and seal the valve to the patient's valve opening.

Claims 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck (6454799) in view of Otto et al. (DE 19532973). Schreck discloses a base **40** with guides **42** on the base for aligning with separate annular body **22**. Schreck discloses the base is formed of a cuff like material, col. 6, lines 54-56. Fig. 2 shows the annular body forming valve members **32**. It can be seen (Fig. 1) that the annular body has a seam **36** and the base has guides that taper to a smaller width at which location is where the assembled valve would be considered together as shown in Fig. 2. A connector **76** is used in connecting portion **70** of annular body of which is connected to

the base via connector portion **54**. It can be construed that the connector **76** provides a tactile marker since the connector slides into to the receptacle of the annular body and then abuts the ledge of the guide, see Fig. 3. Fig. 6 shows the base member and annular body disconnected. However, Schreck fails to disclose the bodies of the prosthesis are of a multi-lobular shape. Otto et al. teach (figs. 1,2) that the prosthesis is designed with a multi-lobular shape to correspond to the anatomy in which it is placed, see abstract and translation of Fig. 1. It would have been obvious to one of ordinary skill in the art to use a multi-lobular shape as taught by Otto et al. for the components of Schreck's valve prosthesis such that it more closely matches the anatomical location to which it is implanted in.

Claims 18,21,22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck '799 in view of Otto et al. (DE 19532973) as applied to claim 11 above, and further in view of Lane '983. Schreck in view of Otto et al. is explained above. However, Schreck as modified by Otto fail to disclose the use of tethers. Lane teaches that in some heart valve assemblies a tether can be used to align the annular body with the base member, col. 7, lines 60-67. It would have been an obvious expedient to use tethers as taught by Lane with the prosthesis of Schreck as modified by Otto et al. such that it gives the surgeon more control of the valve assembly at particular locations and thus provides predictable results.

Claims 19,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schreck '799 in view of Otto et al. (DE 19532973) and Lane '983 as applied to claim 18 above, and further in view of Macoviak (6893459). Schreck as modified by Otto and

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Lane is explained supra. However, Schreck in view of Lane and Otto fail to teach a ratchet mechanism for aligning the annular body with the base member. Macoviak teaches (Figs. 3,4) that one of the base member or annular body has a guide member **67** and the other component has ratchets **43** and the guide member in a guide channel **77**. Macoviak also teaches that the ratcheting provides the surgeon the ability with controlled placement of the valve member at the annulus, col. 6, lines 20-31. It would have been obvious to one of ordinary skill in the art to use ratchets as taught by Macoviak with the valve assembly of Schreck as modified by Otto and Lane such that it provides a predictable control mechanism that maintains set positions while adjusting the components.

Response to Arguments

Applicant's arguments filed 12/18/07 have been fully considered but they are not persuasive. Applicant's arguments with respect to claims 1,11 have been considered but are moot in view of the new ground(s) of rejection.

Applicants argue claims 36 and 52 rejected over Lane '983 that Lane fails to disclose the guide members allow sliding movement. However, the Examiner interprets the guide members or pins in Lane's device do slide along the valve member when inserted therein. The Applicants also argue that Lane attach these components together during assembly. However, it is irrelevant as to when the sliding occurs, just so long as it is capable of. Applicant additionally argues that Lane only has one frame that is

multilobular, however, the use of multiple pieces to form a multilobular shape can be considered to provide a frame with multi-lobular dimensions and since the language of the claim uses comprises, it does not exclude the use of multiple elements to form the structure. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the components forming the valve assembly are separate during implantation) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant argues Schreck's valve assembly components are separate during manufacturing. However, this is a moot point since they are still considered separate and disconnected as admitted by Applicant's arguments, but are used differently. It should be noted that the claims are directed to a product claim and not a method of use. In order to differentiate apparatus from prior art, sufficient structure must be claimed rather than intended uses.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738